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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,790	06/10/2005	Motoyuki Tagashira	TAGASHIRA2	4287
1444 7590 05/22/2009 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			EXAMINER RAO, SAVITHA M	
			ART UNIT 1614	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/538,790	Applicant(s) TAGASHIRA ET AL.	
	Examiner SAVITHA RAO	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 6-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 6-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1 and 6-10 are pending

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/26/2009 is entered.

Applicant's amended claims submitted on 02/26/2009 are acknowledged. Claims 2-5 were cancelled and new claims 6-10 were added.

Applicants' arguments, filed 02/26/2009, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112

(New matter rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 8 and dependent claims 6-7 and 9 are rejected under 35 U.S.C.

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112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 recites "transparent liquid" which is obtained upon subjecting the concentrate to at least one of centrifuging and filtering" in the penultimate line of the claim. The disclosure as filed refers to this step as follows

"The resulting hop bract extract is a green to white green liquid. Then, the liquid is concentrated into a residual alcohol concentration of 2 v/v% or less and purified. If the concentrate is not purified and it is treated in the next process, since a large amount of precipitates derived from wax and fibers are produced, serious troubles are caused in working (specification page 3, line 3-6) and that " The purification process is conducted by centrifuging or filtering the hop bract extract which is concentrated into a residual alcohol concentration of 2 v/v% or less. In the centrifuging process, a common centrifuge may be a continuous type or a centrifuge tube type without any problems. A continuous type centrifuge having centrifugation at 15 about 50-10,000G may be preferably used" (specification page 3, lines 11-15).

In neither of the above instances does the disclosure mention obtaining a "transparent liquid" in relation to concentration by centrifuging or filtration step.

Instant claim 8 also contains New Matter in that the increase in purity caused by the synthetic gel absorbent is only disclosed via "washing" as noted in the spec. on page 3, lines 33-34.

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Accordingly, claim 1 and 8 and dependent claims 6-7 and 9 are properly rejected under 35 U.S.C. 112 for new matter addition in the claims.

Claims 1 and dependent claims 6-9 is further rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In instant claim 1, line 8, it is unclear whether the obtaining of a transparent liquid is only associated with filtering or whether it is also what is obtained when centrifuging is performed.

Claim Rejections - 35 USC § 102(b)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Motoyuki et al (Biosci. Biotech. Biochem. 61 (2) 332-335 (1997), reference already on record.

Instant claims 10 is drawn to a process for producing hop bract polyphenol extracting hop bract with an aqueous alcohol solution, concentrating the extract to give a residual alcohol concentration of 2 v/v% or less, and purifying the concentrate.

Motoyuki discloses preparation of the hop bract polyphenols where the bracts were extracted with 2 liters of 30% ethanol aqueous solution. After filtration and evaporation of the ethanol, the extract was lyophilized to give a light-green residue. The residue was purified by dissolving in 1 liter of distilled water and passing it through a

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styrene-divinylbenzene resin column, for 60 minutes. The column was washed with water and polyphenol was eluted with ethanol aqueous solution stepwise. After evaporation of the ethanol, each fraction was lyophilized to give light-brown powder of hop bract polyphenol (page 332, Materials and Methods, left column, last paragraph).

With regards to the instant claim 10 limitation wherein the residual alcohol concentration was 2% v/v before the final purification method, Motoyuki is silent as to the final alcohol content of his preparation. However, since the procedure for preparation of the Hop Bract polyphenols is identical to the instantly claimed method and additionally, Motoyuki's process involves evaporation and lyophilization of the extracted polyphenol before it is purified, any traces of alcohol if present would be as low as or lower than that instantly claimed. Absence of any evidence to the contrary, prior art hop bract polyphenol would exhibit the same properties as that claimed in the instant claim 1. It is incumbent upon the applicant to provide evidence or comparative data to the contrary.

Motoyuki's disclosure of evaporation of the ethanol after the filtration step anticipates the concentration step, since evaporating a solvent from an extract naturally tends to concentrate the extract.

Accordingly, Motoyuki anticipates instant claim 10

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Motoyuki et al (Biosci. Biotech. Biochem. 61 (2) 332-335 (1997), reference already on record.

Motoyuki discloses preparation of the hop bract polyphenols where the 80 g of bracts (containing **less than 0.5% of lupulin** glands) were extracted with 2 liters of **30% ethanol** aqueous solution at **80°C for 40 minutes**. After filtration and evaporation of

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the ethanol, the extract was lyophilized to give a light-green residue. The residue was purified by dissolving in 1 liter of distilled water and passing it through a styrene-divinylbenzene resin column, for 60 minutes. The column was washed with water and polyphenol was eluted with 10%, 50% and 80% ethanol aqueous solution stepwise. After evaporation of the ethanol, each fraction was lyophilized to give light-brown powder of hop bract polyphenol (page 332, Materials and Methods, left column, last paragraph to right col., 1st paragraph).

With regards to the instant claim 1 and 10 limitation wherein the residual alcohol concentration was 2% v/v before the final purification method, Motoyuki is silent as to the final alcohol content of his preparation. However, since the procedure for preparation of the Hop Bract polyphenols is identical to the instantly claimed method and additionally, Motoyuki's process involves evaporation and lyophilization of the extracted polyphenol before it is purified, any traces of alcohol if present would be as low as or lower than that instantly claimed. Absence of any evidence to the contrary, prior art hop bract polyphenol would exhibit the same properties as that claimed in the instant claim 1 and 10. It is incumbent upon the applicant to provide evidence or comparative data to the contrary.

With regards to the limitation in instant claim 1 where in the concentrate is subjected to at least one of centrifuging and filtering to obtain a transparent liquid, It is generally known by one of ordinary skill in the art that extraction of active principles from plant materials involves separation of the unwanted solid material from the fraction comprising the active principle. Separation using centrifugation and filtration for this

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purposes before the product goes through additional purification steps is well known in the art. Greater care in achieving the initial separation from the unwanted material before column purification, higher the yield of the active material as the additional separation step prevents the column clogging with unwanted materials and thereby provides purer material of higher yield. Accordingly, it would be obvious for one of ordinary skill in the art to utilize different centrifuging and filtrations procedures in developing a method of purification of different extracts.

With regards to instant claim 6 which recites the limitation that "prior to the extraction, lupulin is removed from the hop bract" Motoyuki's teaches the hop bracts in his preparation to contain less than 0.5% of lupulin glands which clearly suggest to an ordinarily skilled artisan that lupulin was removed before the extraction process taught by Motoyuki.

With regards to the limitation claimed in instant claim 7 which claims the concentrations of the aqueous alcohol solution to be at 50v/v %, the weight ratio of hopbract to aqueous alcohol solution to be between 1: 10-20 and the conditions of the extraction which is at a temperature of 30-60°C for 60-18 minutes. Although Motoyuki does not teach these specific concentration or conditions. However, Motoyuki teaches the alcohol solution to be at 30% v/v, the ratio of hopbract to alcohol solutions to be 1: 25 and the extraction condition to be at a temperature of 80°C for 40 minutes.

Accordingly it would be within the skill of an ordinary artisan to be able to modify aqueous alcohol concentration, the ratio between hopbract and aqueous alcohol and the extraction conditions to obtain the purest form of hop bract polyphenols. It is noted

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that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Motoyuki's disclosure of evaporation of the ethanol after the filtration step anticipates the concentration step recited in instant claims 1 and 10 since evaporating a solvent from an extract naturally tends to concentrate the extract.

With regards to the limitations of instant claim 8 and 9. The synthetic gel absorbent taught by Motoyuki for final purification of the extract as stated above is the same as the instantly claimed synthetic gel adsorbent which is the "styrene divinylbenzene resin column" (instant specification, page 3, lines 28-31) . Accordingly, the functions of this particular synthetic gel adsorbent which is claimed in instant claims 8-9 would inherently be present in the similar gel used by Motoyuki et al. A composition and its properties cannot be separated. It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Conclusion

Claims 1 and 6-10 are rejected. No claims are allowed

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAVITHA RAO whose telephone number is (571)270-5315. The examiner can normally be reached on Mon-Fri 7 am to 4 pm..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached at 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SAVITHA RAO/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614